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(54) **Surgical fluid evacuator: its use and components therefor.**

(57) A surgical fluid evacuator comprises a flexible, compressible reservoir which draws a substantially constant vacuum to permit uniform removal of fluid from a surgical incision through a wound drain catheter. The reservoir comprises a pair of congruent, articulated plates (10a, 10b) having the area between them sealed from the atmosphere by a flexible membrane 40. A spring (14) between the plates (10a, 10b) biases them apart to create a vacuum in the reservoir. As the reservoir, and spring, expands to draw fluid the articulated plates hinge to vary the shape of the reservoir to at least partially offset the decreasing force of the spring on the plates.

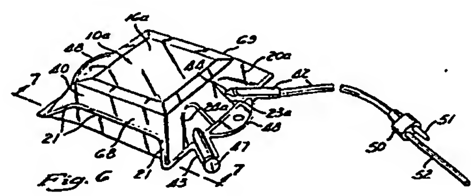

Fig. 6

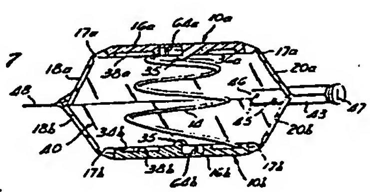

Fig 7

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DESCRIPTION

SURGICAL FLUID EVACUATOR: ITS USE AND COMPONENTS THEREFOR

This invention relates to portable fluid evacuators which are disposable and self-contained.

The practice of drawing a vacuum on a catheter placed in a patient's body to remove fluid buildup following surgery is a common medical technique. It has been found that removal of fluids from a wound will accelerate healing and reduce the risk of infection. Fluid evacuation has been typically accomplished by means of a central suction system or by power driven vacuum pumps. This has proven unsatisfactory because it is difficult or impossible to move the patient without first disconnecting him from vacuum supply. Further, the negative pressure supplied by such vacuum units is difficult to maintain at a constant value. Moreover, the use of power driven electric pumps is potentially hazardous since the fluid pathway through the wound drain catheter creates an electrical connection between the pump and the patient which exposes the patient to risk of shock or electrocution.

The prior art attempted to overcome these problems by providing portable, self-contained, non-electrical fluid evacuators. These evacuators typically comprise collapsible reservoirs biased with springs or weights which bias them to open after being manually compressed. Since these devices are self-contained and portable, the patient may be easily moved without disconnecting him from the device. However, many of these prior art devices are not capable of maintaining a substantially constant vacuum over their entire filling range. Constant vacuum pressure is desirable, since this permits uniform removal of fluid from the patient. If the vacuum is too high, lesions may be caused by sucking

delicate tissue into or against the drainage tube. Conversely, if the vacuum is too low, fluid will accumulate and the device will be ineffective. Thus a substantially constant pressure fluid evacuator is considered highly advantageous.

A further problem with prior art evacuators is that many of them are not pre-evacuated by the manufacturers, but rather, must be manually evacuated just prior to use. Typically, a nurse or medical assistant will apply force with one hand to manually compress and collapse the reservoir , and, with the other hand, insert a catheter or plug into the device before removing such compression force. Evacuation at the point of use is, therefore, awkward and time consuming.

An additional disadvantage of fluid evacuation devices which are evacuated at their point of use is that they are shipped in an unevacuated state. Thus, they require more storage space than the pre-evacuated devices. Obviously, this increases shipping, storage, and sterilization costs. Further, it is difficult, if not impossible, to completely evacuate a fluid reservoir at its point of use. Thus, when the reservoir is initially connected to draw fluid from the patient, it may still contain a substantial quantity of air. Since the space devoted to containing such air is wasted, the effective capacity of the reservoir is decreased. Therefore, the reservoir size must be larger than would otherwise be necessary. This increases manufacturing costs and further increases the costs of sterilization, shipment, and storage.

One reference, U.S.Patent No.4,161,179 (Abramson) suggests pre-evacuating a fluid evacuation device. The Abramson device comprises a flexible reservoir biased with leaf springs. Abramson teaches that after the reservoir has been pre-evacuated, the catheter is

is clamped to maintain the vacuum created by such pre-evacuation. Subsequently, after the catheter has been placed in the wound, the clamp is removed to permit the device to draw fluid. However, this method of maintaining a vacuum is obviously disadvantageous, since the clamp may be accidentally dislodged either during shipment or by a nurse while handling the device. Moreover, such a clamp, in order to maintain the vacuum, would have to exert considerable force on the catheter tube. Thus, if the device were stored for a long period of time, the resiliency of the catheter tube may not be sufficient to permit it to return to its normal shape, and the tube may remain permanently crimped. Therefore, the flow of fluid from the wound to the evacuator would be substantially restricted.

One object of the present invention is to provide a device which can alleviate these problems of the prior art by providing a reservoir which may draw a substantially constant negative pressure.

According to the invention there is provided a surgical evacuation device for drawing fluid from a wound comprising a compressible reservoir which comprises a flexible membrane, first and second articulated walls which co-operate to form an articulative structure for supporting the membrane, and a spring between said walls for biasing them apart to expand the reservoir and create a vacuum therein, and whose force on the walls decreases as the reservoir expands, the articulative structure defining a shape for the reservoir which varies as the reservoir expands to at least partially offset the decreasing force of the spring to reduce changes in reservoir vacuum.

The variation in the shape of the structure decreases the effective wall area acted upon by the force of the spring. The variation permits atmospheric forces

on the articulated walls to provide a correspondingly varying supplementary force to assist the spring in biasing the walls apart, the supplementary force increasing as the reservoir expands to co-operate with the force of the spring to reduce changes in vacuum as the reservoir expands.

In a preferred embodiment the membrane, which seals the area between the articulated walls from the atmosphere, comprises a plastics bag containing and sized to the articulative structure. The articulated walls comprise a pair of congruent, superimposed, hinged plates, each plate comprising a generally square or rectangular central member hingeably connected at opposite edges between wing members, each wing member having a generally isosceles trapezoidal shape with its longest side remote from the central member, two of said longest sides being hingeably connected to form the articulative structure.

The invention also embraces an articulated plate for use as a component in a surgical evacuation device according to the invention and adapted to form at least a part of the articulative structure therein, the plate comprising a generally square or rectangular central member hingeably connected to opposite edges between wing members, each wing member having a generally isosceles trapezoidal shape with its longest side remote from the central member and said longest side having means for hingeable connection with the corresponding side of another plate.

The present invention thus provides a preferably pre-evacuated flexible reservoir which houses an articulated, spring biased, skeletal mechanism. The skeletal mechanism and the reservoir co-operate to permit the reservoir to draw a vacuum at a substantially constant

negative pressure. An internal latch is preferably included within the skeletal mechanism to maintain the reservoir in a compressed, evacuated condition prior to use.

In preferred embodiments: The skeletal mechanism comprises a substantially conical helical spring, interposed between two articulated walls or plates. The spring biases the plates in opposite directions. Each of the plates includes a generally square or rectangular central member that is connected on opposite sides to respective wing members by integral hinges. Each of the two wing members is generally shaped as an isosceles trapezoid, and one of the two wing members has a pair of triangular notches. The central member and two wing members of each plate are of the same dimensions to permit the plates to be congruent. The plates are retained in a congruent position by means of one or more hinges on the ends of the unnotched wing members of the respective plates. Since the hinges are at the end of the unnotched wing members, they do not prevent the central members and two wing members from pivoting relative to each other as the reservoir fills.

The central members each have a spring cup to permit the spring to be retained therebetween. When the plates are pressed against one another, the individual coils of the conical biasing spring compress to nest within one another and within the recesses of the spring cups. Thus, when the spring is fully compressed, the two plates lie flat against each other with virtually no space therebetween. A latch is included within each of the respective spring cups to retain the spring, the skeletal mechanism, and the reservoir in a compressed state.

The plates, with the spring compressed therebetween, are sealed in the reservoir which comprises a rectangular

plastic bag. The bag is limp or flexible, is sized to fit the overall length and width of the plates, and is stretched to ensure that the plates fit snugly therein. Since the latch holds the spring in a compressed state, the plates lie flat against one another, thereby permitting the device to be manufactured and shipped in a thin, compact, and pre-compressed state. This significantly reduces the cost of sterilization, shipment, and storage. Further, such pre-compression eliminates the task of evacuating the device at its point of use by manually compressing it.

Although not essential, it is preferable to draw a vacuum on the reservoir after it is compressed and latched, but prior to shipment to the consumer. This is a convenient method of removing residual pockets of air from the reservoir. Further, such vaccuum permits atmospheric pressure to exert force against the exterior surfaces of the two plates. This assists the latch in maintaining the device in a compressed state, and thereby reduces stress forces on the latch. Thus, the device may be stored in its pre-evacuated state for long periods of time without deformation of the latch mechanism. In addition, the vacuum effectively immobilizes the latch and thereby reduces the risk of accidental or inadvertent disengagement.

The reservoir includes a drain tube and a fluid collection tube which pass through the reservoir wall into the triangular notches, respectively, of the notched wing members. At the points where these tubes pass through the reservoir, they are sealed to the reservoir. These tubes extend well into the reservoir to reduce the likelihood that the reservoir wall might interfere with the flow of fluid. The fluid collection tube includes a check valve to prevent reverse flow of

fluid from the reservoir to the patient. The drain tube includes perforations along its extension into the reservoir to assure that the reservoir will be completely drained even if the end of the drain tube is blocked. A plug or stopper is provided to seal the drain tube when not in use.

The end of the fluid collection tube outside the reservoir is terminated in a Y-fitting to permit the fluid evacuation device to be connected to one or two catheters. The Y-fitting is normally sealed to maintain the previously discussed vacuum in the reservoir. However, just prior to insertion into the catheter, a nurse or medical assistant will remove this seal. Thus, a small amount of air is permitted to enter the reservoir through the unsealed Y-fitting. Such air will not destroy the sterility of the device, since the Y-fitting seal is typically broken in an operating room environment. Further, the amount of air entering the reservoir is so small that it will have little, if any, effect on the fluid capacity of the device. However, the amount of air is sufficient to break the vacuum, and thereby permit the latch to function.

After the fluid collection tube is connected to the catheter, the surgical evacuator is activated simply by bending the unnotched wing members relative to the central members. Such bending causes the central plates to slide relative to one another, and thereby disengages the latch. This releases the conical spring, and thus, the spring will force the plates apart. As the distance between the plates increases, the volume of the reservoir will concommitantly increase. However, since the reservoir is sealed from the atmosphere, the volume of the reservoir cannot increase unless it draws fluid from the catheter. Thus, as the plates are forced apart, a suction or vacuum will be created to draw fluid into the reservoir.

The nominal value of reservoir vacuum for fluid evacuation purposes is typically 6895 Pa. It was a primary design consideration in the present invention to limit deviations in vacuum to less than 20% from the nominal value in the belief that such limitation will virtually eliminate the risk that the vacuum will cause lesions by sucking tissue into the catheter's drain tube. Further, it is believed that such limitation in vacuum pressure will ensure that the device will have sufficient suction to prevent excessive fluid buildup. Accordingly, the present invention is designed to limit deviations in vacuum to ±20% throughout its operating range. This is accomplished both by the design of the spring and the unique geometry of the plates. As discussed above, the spring is conical to permit it, when compressed, to nest in the spring cups. Thus, the diameter of the spring coils will vary from one end to the other. It is well known that for a given type of spring material, the spring constant (i.e., the slope of the force versus distance curve) varies inversely according to the coil diameter. Thus, a conical spring typically has a non-linear spring constant. However, it is also well known that the spring constant varies directly with the pitch of the spring coils. Thus, the inherent non-linearity of the spring constant of a conical spring may be compensated for by varying the pitch of the spring coils. Accordingly, by increasing the pitch of the coils as the coil diameter increases, the spring of the present invention is formed to have an essentially linear spring constant.

The force exerted by the coils of a conical spring having a linear spring constant is directly proportional to the amount that they are compressed. Thus, as the conical spring forces the plates apart, the force exerted by such spring will progressively, linearly

decrease as the distance between the plates increases. Such decrease in the force exerted by the spring is compensated for by the unique geometry of the plates. Specifically, it will be recalled that the plates are articulated by hinging each pair of wing members to its respective central member. Thus, as the central members are forced apart, their respective pair of wing members will pivot inward. Such inward movement of the wing members permits the spring to exert force over a progressively smaller effective plate area. Since both the spring force and this effective plate area decrease as the plates separate, the force per unit of area remains more nearly constant. Thus, such articulation of the plates compensates for the progressive decrease in spring force.

In addition, it will also be recalled that the reservoir is sized to fit snugly around the plates. Thus, the vacuum created ty the expanding volume of the reservoir will force the reservoir wall inward against the articulated plates. Assuming that the central members lie in the horizontal plane, the horizontal component of the force exerted by the reservoir wall on the wing members will increase and the vertical component will decrease, as the wing members pivot inward at progressively increasing angles with respect to the central members. This horizontal force on the wing members will drive the wing members inward. Since the wing members are integrally hinged to the central members, the wing members will wedge against the central members to force them apart. Thus, such wedging force by the wing members against the central members further compensates for the loss of spring force as the central members spread apart. Therefore, the unique geometry presently proposed permits the spring force per unit of effective area to remain substantially constant, and

thereby limits vacuum pressure deviations to $\pm 20\%$ to permit maintenance of a substantially constant negative pressure throughout the entire filling range of the device.

The invention is described further hereinafter, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is an exploded perspective view of the articulated plates of a device in accordance with the present invention, with the spring interposed therebetween;

Figure 2 is a perspective view of the plates, with the spring compressed therebetween, sealed in a flexible reservoir having a fluid collection tube and drain tube;

Figure 3 is a cross-sectional view of an evacuator of the present invention in its compressed state, taken along the lines 3-3 of Figure 2;

Figure 3A is a partial, enlarged view of one wing portion of Figure 3, showing the hinged connection between the central members and one pair of wing members in greater detail;

Figure 3B is the same partial enlarged view of Figure 3A showing the hinged connection interacting with the central members to slide the central members in opposite directions in response to bending the pair of wing members relative to the central members;

Figure 4 is an enlarged, partial cross-sectional view of the plates 10, taken along the lines 4-4 of Figure 2, showing the latch hooks engaging each other;

Figure 5 is the same enlarged partial cross-sectional view of Figure 4 showing the latch hooks disengaged as the plate 10 slides relative to each other according to Figure 3B;

Figure 6 is a perspective view of the evacuator after the reservoir has expanded to its maximum volume;

Figure 7 is a cross-sectional view taken along the lines 7-7 of Figure 6, with part of the plates cut away to illustrate the position of the latch hooks on their respective plates;

Figure 8 is a graph of spring force versus distance from full compression for a typical helical spring and for an ideal spring;

Figure 9 is a schematic cross-sectional view of an evacuator of the present invention, illustrating the forces acting on the articulated plates and defining some of the geometric relationships and characteristics of the plates;

Figure 10 is a graph of spring force versus distance from full compression which approximates the spring characteristics necessary to achieve a constant reservoir vacuum for a given plate geometry;

Figure 11 is a graph of spring coil pitch versus spring coil diameter for a single coil spring of a given material and for a given spring force at maximum compression; and

Figure 12 is a graph showing reservoir vacuum versus volume of fluid drawn into the reservoir for a given plate geometry and a spring having given characteristics.

Referring to Figure 1, the present invention comprises a pair of congruent, articulated plates 10a and 10b with a conical helical spring 14 interposed therebetween. Each of the plates 10a,10b includes a respective square or rectangular central member 16a,16b which is connected by integrally formed hinges 17a,17b to respective trapezoidal wing members 18a,18b and 20a,20b. The trapezoidal wing members 18,20 are disposed on opposite sides of the central members 16 and have an

isosceles configuration, with the shorter of their trapezoidal bases being hinged to the central member 16. Thus, the plates 10 are shaped substantially as rectangles with trapezoidal cut-outs 21,22 (Fig.2) on opposite sides. The wing members 20a and 20b include a pair of essentially triangular notches 23a, 24a and 23b 24b, respectively, while the wing members 18a and 18b are not notched. However, the wing member 18a includes a pair of upstanding hinge hooks 26 which are sized to be received by a pair of slots 28 in the wing member 18b.

The plates 10a and 10b include respective inverted spring cups or bosses 32a and 32b and respective recessed spring cups 34a and 34b. The spring boss 32 is sized to retain the small coil diameter end of the conical spring 14 while the spring cup 34 is sized to retain the large coil diameter end of the conical spring 14. Each of the plates 10 has both an inner spring boss 32 and an outer spring cup 34. Thus, either of the plates 10 may receive either end of the spring 14.

To assemble the evacuator, the plates 10a,10b are first hinged together, by inverting the plate 10a, inserting the hinge hooks 26 into the slots 28, and then rotating the plate 10a about the hooks 26. This assembly operation results in a congruent positioning of the plates 10, with a hinged connection therebetween at 30 (Figure 2). The spring 14 is next compressed between the spring cups 32,34 of the plates 10.

The spring cups and bosses 32a,34a and 32b,34b form recesses 38a and 38b, respectively, in the plates 10a and 10b, respectively, to permit the fully compressed spring 14 to nest therein, and thereby permit the plates 10 to lie flat against each other with virtually no space therebetween (Figure 3). A latch member or hook 36b, which protrudes from the interior face of the plate

10b, is provided within the spring boss 32b. The plate 10a has a similarly disposed latch member or hook 36a oriented 180 degrees with respect to the latch hook 36b. These latch hooks 36 form a latch 35 which retains the spring 14 in a compressed condition.

Referring to Figure 2, the plates 10 with the compressed spring 14 retained therebetween are sealed in a rectangular membranous reservoir or plastic bag 40. The reservoir 40 is sized to fit the overall dimensions of the compressed plates 10. Further, the reservoir 40 is stretched in a direction shown by the arrow 41 to ensure that the bag fits snugly around the plates 10. Since the plates 10 are not solid rectangles because of the trapezoidal cut-outs 21,22, the plates 10, therefore, will not contact the entire surface of the rectangular reservoir 40. As will be understood more fully below, the trapezoidal cut-outs of the plates 10 are included to permit the reservoir 40 to expand in volume as the device draws fluid from the patient.

A fluid collection tube 42 and drain tube 43 are connected to the reservoir 40. Both of the tubes 42,43 are sealed to the reservoir 40 at the point where they pass through the reservoir wall into the triangular notches 23,24, respectively, of the wing members 20. These tubes 42,43 extend well into the reservoir to reduce the likelihood that the reservoir wall will interfere with the flow of fluid. A check valve 44 is included on the end of the fluid collection tube 42 within the reservoir 40 to prevent reverse flow of fluid from the reservoir 40 to the patient. The drain tube 43 includes perforations 45 (Figure 7) along its extension into the reservoir 40 to permit the reservoir 40 to be completely drained even if the end of the tube 43 is blocked. A plug or stopper 47 seals the drain tube when not in use.

The reservoir 40 also includes a pair of flanges 48 to permit the reservoir to be attached to the patient by a strap (not shown). The end of the fluid collection tube 42 is terminated in a Y-fitting 50 having two catheter connections 51 to permit it to be connected to one or two wound drain catheters 52. The Y-fitting 50 is normally sealed to prevent ambient air from entering the reservoir 40. However, just prior to connecting the catheter 52, a nurse or medical assistant will remove this seal, typically by cutting the end of the catheter connector 51.

The device may be precompressed by the manufacturer prior to shipment. As previously mentioned, the latch 35 retains the device in a precompressed state. However, it is preferable to also draw a vacuum on the reservoir 40 prior to shipment to completely evacuate any residual air contained in the reservoir 40. This vacuum permits atmospheric pressure to exert force on the walls of the reservoir 40 and thereby assists the latch 35 in maintaining the plates 10 in a precompressed state. Thus, stress forces on the latch hooks 36 are reduced and therefore the device may be stored in its pre-evacuated, precompressed state for substantial periods of time without deformation of the latch 35. Such precompression by the manufacturer also permits the device to be very compact, since the thickness of the device, when compressed, is equal to the combined thickness of the plates 10, typically about 9.5 mm.

As will be understood more fully below, the vacuum prevents relative movement of the latch hooks 36 and thereby reduces the risk of accidental or inadvertent disengagement of the latch 35. Thus, when the evacuator is to be used, in order to disengage the latch 35, the vacuum must be broken. This is typically accomplished by breaking the previously described seal on the catheter

connector 51 of the Y-fitting 50, thereby permitting a small amount of air to enter the reservoir 40. Since the seal is typically broken in an operating room environment, the sterility of the device will not be affected. Further, the quantity of air entering the reservoir is so small that its effect on the fluid capacity of the reservoir is insignificant. However, the quantity of air is sufficient to break the vacuum and thus permit the latch 35 to function.

Referring now to Figures 4 and 5, the details of the latch 35 will be described. As previously mentioned, the latch 35 is comprised of latch hooks 36a and 36b, which extend from the interior of the plates 10a and 10b, respectively. The plates 10a and 10b have respective cavities 54a and 54b which receive the latch hooks 36b and 36a, respectively. The latch hooks 36a and 36b have respective hooking surfaces 56a and 56b which engage each other to hold the plates 10 against one another, as shown in Figure 4. These hooking surfaces 56 are inclined slightly relative to their respective paltes 10 to inhibit them from sliding relative to each other, and thereby disengaging.

Referring to Figure 3, the latches 35 may be disengaged by grasping the plates 10 between the fingers and thumb (shown in phantom) and bending the wing plates 18 upward with respect to the central plate 16. Such disengagement of the latch 35 is accomplished by forming the hinges 17 as semicircular slots which are disposed to face each other to form a cylindrical opening, as shown in Figure 3A. Referring to Figure 3B, as the wing members 18 pivot upward relative to their respective central members 16, the width of the slot forming the hinge 17a will decrease and the width of the slot forming

the hinge 17a will concomitantly increase. Since the ends of the wing members 18 are connected together by the hinge 30, they will necessarily remain in a congruent position. Thus, the decreasing width of the slot of the hinge 17b will tend to slide the central member 16b towards the wing members 18 and the increasing width of the slot of the hinge 17a will tend to slide the central member 16a away from the wing members 18. Therefore, the central members 16 will slide relative to each other. Since the latch hooks 36a and 36b are attached to the central members 16a and 16b, respectively, they will also slide relative to each other. Such sliding is sufficient to change the position of the latch hooks 36 from that shown in Figure 4 to that shown in Figure 5, and thus permit the hooking surfaces 56 to disengage. Therefore, the latch 35 may be disengaged simply by bending the wing members 18 relative to the central members 16. Such disengagement permits the conical spring to separate the plates 10 and thereby enables the device to draw fluid into the reservoir 40.

Although it is preferable to dispose of the device after its first use, the device may, if desired, be drained, compressed, and reused. This is accomplished by removing the drain plug 46, emptying the reservoir 40 by manually pushing the plates 10 against one another to compress the spring 14, and reinserting the drain plug 46. The latch 35 is adapted to re-engage when the spring 14 is fully compressed. This is accomplished by providing respective closing cam surfaces 58a,58b and biasing cam surfaces 60a,60b on the latch hooks 36a,36b. The closing cam surfaces 58 are inclined relative to their respective central members 16, and co-operate to force the biasing cam surfaces 60a,60b against respective resilient biasing tabs 64b and 64a. These tabs 64a and

64b protrude from the respective cavities 54a and 54b of the respective plates 10a and 10b. As the latch hooks 36a and 36b descend into the cavities 54b and 54a, respectively, their biasing cam surfaces 60a,60b will bend the tabs 64b and 64a, respectively, in opposite directions, as shown in Figure 5. When the latch hooks 36 descend sufficiently to permit the hooking surfaces 56a and 56b to clear each other, the resiliency of the tabs 58b and 58a will urge the hooking surfaces 56a and 56b towards each other to force them to engage,as shown in Figure 4. Thus, the biasing tabs 64 co-operate with the latch hooks 36 to engage the latch 35 and thereby retain the spring 14 between the plates 10. These tabs 64 also reduce the risk that the latch 35 may be inadvertently disengaged since it is apparent that their resiliency must be overcome before the hooking surfaces 56 can disengage.

When the latch 35 is disengaged, the compressed conical spring 14 will exert force on the central members 16 to force the plates 10 apart. Since the reservoir 40 is sealed from the atmosphere, such force creates a vacuum which draws fluid from the patient into the reservoir 40. Referring to Figures 6 and 7, as the plates 10 separate, the reservoir 40 will form side walls 68,69 (Figure 6) which conform to the trapezoidal cut-outs 21,22, respectively. The wall 69 is on the opposite side of the reservoir 40 from the wall 68. Since the reservoir 40 is stretched across the cut-outs 21,22 in the direction indicated by the arrow 41, the reservoir walls 68,69 will not be sucked between the plates 10, but rather will remain more or less perpendicular to the plates 10 as the reservoir 40 fills with fluid. This prevents any sudden changes in reservoir vacuum and permits the reservoir 40 to gradually expand in volume as the

plates 10 separate. Thus, the reservoir 40 will have a defined, gradually changing, shape throughout its filling range.

The spring 14 and the unique geometry of the plates 10 co-operate to permit the reservoir 40 to draw a substantially constant vacuum through its entire filling range. "Substantially constant" means that the vacuum level does not fluctuate by more than 20%. Such co-operation may be more fully understood through reference to Figures 8, 9, and 10. Referring initially to Figure 8, it is well known that the force of a compression spring varies inversely to the distance it expands from a fully compressed state. Thus, when a spring is fully compressed, its force is at a maximum, and when it fully relaxes, its force is zero. This relationship is defined by the expression:

$$F = A - KX \qquad (1)$$

where F is the force, A is the force at full compression, K is a constant, and X is the distance the spring relaxes from full compression. This expression is represented graphically by a curve 70 of Figure 8. The constant K is typically referred to as the spring constant, and it defines the slope of the curve 70. It is apparent that, if it were possible to obtain a spring with a spring constant of zero, as indicated by the curve 72, the force exerted by the spring would always be a constant value. Such a spring would make the design of a constant vacuum fluid evacuator a relatively simple matter. For example, it is apparent that a spring with a zero spring constant interposed between two plates connected by bellows could be made to achieve the desired constant vacuum result. Unfortunately, however, a spring having a spring constant of zero would be infinitely long, since the spring, in order to maintain constant force, could

never be permitted to fully relax. Thus, as a practical matter, a compromise must be drawn between the spring constant and the length of the spring.

The unique plate geometry of the present invention permits such compromise. Specifically, the plate geometry compensates for the decreasing spring force as the spring 14 expands from a fully compressed state and thereby permits maintenance of a substantially constant pressure within the reservoir 40. It will be recalled that each of the plates 10 is articulated by hinging the wing members 18,20 to their respective central members 16. Comparing Figures 2 and 3 with Figures 6 and 7, it can be seen that, as the plates 10 are forced apart by the spring 14, the wing members 18, 20 pivot inward with respect to the central members 16. This permits the effective plate area over which the spring force is applied to concommitantly decrease. Thus, the effective plate area decreases as the spring force decreases, and therefore, the force per unit of effective area remains more nearly constant. Since the vacuum within the reservoir 40 is proportional to the force per unit area applied to the plates 10, the vacuum will also be more nearly constant.

The geometry of the plates 10 also supplements the spring force as the wing members 18,20 pivot inward. This may be understood more fully by comparing the position of the wing members 18,20 with respect to the central members 16, shown in Figure 3, with that shown in Figure 7. Referring initially to Figure 3, when the spring 14 is fully compressed, the wing members 18,20 lie in the same horizontal plate as the central members 15. Thus, the forces generated by the spring 14 between the plates 10 and the opposing forces created by atmospheric pressure will both be directed vertically.

However, as the wing plates 18,20 pivot inward, as shown in Figure 7, it is apparent that the direction of the opposing atmospheric forces applied to the wing members 18,20 will incline from the vertical toward the horizontal. Thus, the forces on the wing members 18,20 will have a decreasing vertical component and an increasing horizontal component, as they pivot inward at progressively increasing angles with respect to the central members 16. Such horizontal component will drive the wing members 18,20 inward. Since the wing members 18,20 are connected to their respective central members 16 by the hinges 17, the inward movement of the wing members 18,20 will result in a force which will wedge the central members apart. Thus, the spring force is supplemented by such horizontal forces on the wing members 18,20.

The reservoir 40 also interacts with the wing members 18,20 to supplement the horizontal component force, described above, to drive the wing members 18,20 inward and the central members apart. It will be recalled that the reservoir is stretched between the ends of the wing members 18,20, and across the trapezoidal cut-outs 21,22 to permit the reservoir side walls 68,69 (Figure 6) to remain more or less perpendicular to the central members 16 as the plates 10 spread apart. Thus, atmospheric pressure will exert force against such perpendicular reservoir walls 68,69. This will pull the ends of the wing members 18,20 toward each other and thereby provide a supplementary force which assists in driving the wing members 18,20 inward. In addition, since the reservoir 40, as previously mentioned, is stretched between the ends of the wing members 18,20, such stretching will provide a further supplementary force to pivot the wing members 18,20 inward relative to the central members 16.

and wing members 18,20 dimensions of 95.3 mm by 146 by 34.9 mm is illustrated by the curve 74 of Figure 10. While the curve 74 is not exactly linear, it approaches linearity through $\theta = 45$ degrees. Further, it is believed that the previously described interaction of the reservoir 40 with the plates 10 increases the linearity of the curve 74 through this operating range of the reservoir 40. Test results also support the conclusion that the curve 74 is, in reality, more linear than the mathematical approximation illustrated by Figure 10. Thus, a spring having a linear force versus distance relationship will approximate the force versus distance characteristics of the curve 74. Further, the slope of the curve 74 is sufficiently steep to permit such spring to be of a reasonable length. It should be noted, however, that the curve 74 may be approximated by a linear curve only from zero degrees to 45 degrees of the angle theta. Beyond 45 degrees, the deviation between the curve 74 and a linear curve rapidly increases. Thus, if the distance between the central plates 16 increases significantly beyond a theta of 45 degrees, such deviation will cause the negative pressure within the reservoir 40 to vary substantially from its desired constant value. To avoid this, the trapezoidal cut-outs 21,22 formed by the central members 16 and wing members 18 and 20 of the respective plates 10 are sized to limit the maximum volume of the reservoir 40 to a value which limits the maximum distance between the central members 16 to the equivalent of 45 degrees of the angle theta. This requires that the depth of the cut-outs 21,22 represented by the dimension 80 (Figure 2) be one-half of the maximum distance between the central members 16. Such maximum distance, which is also equal to the maximum height of the side walls 68,69 (Figure 6), may

be calculated by using equation (7), discussed in reference to Figure 9, and substituting 45 degrees for theta. Thus,

given that: $X_R = 2H_W \sin\theta$, and $\theta = 45$ degrees.

then: $X_R = 2H_W(.707)$

or: $X_R = 1.414H_W$.

Since the dimension 80 of the cut-outs 21,22 is one-half of the distance between the members 16 when theta is 45 degrees, or one-half of $1.414H_W$, such dimension, therefore, is equal to .707 H_W, where H_W (Figure 9) is the trapezoidal height of one of the wing members 18,20. Thus, by sizing the depth of the cut-outs 21,22 to equal .707 H_W, the maximum distance between the plates 16 is limited to the equivalent of 45 degrees of the angle theta.

As previously mentioned, the curve 74 of Figure 10 may be approximated by a spring having a linear force versus distance relationship. However, it will be recalled that such approximation is valid only from zero degrees to 45 degrees of theta. Thus, to take full advantage of the unique plate geometry, the spring should preferably be under full compression when theta equals zero degrees. Since the plates 10 lie flat against one another when theta equals zero degrees, the spring, therefore, should be conical to permit it to be compressed flat therebetween. It is well known, however, that the strength of a spring coil is inversely proportional to its diameter. The coils of a conical spring, therefore, typically vary in strength, since their diameters necessarily vary. Thus, upon expansion, the coils become progressively active, rather than simultaneously active, and the force versus distance relationship of the spring is consequently non-linear. Therefore, a typical conical spring is incapable of

providing the linear force versus distance relationship necessary to approximate the curve 74.

The conical spring 14 of the present device, therefore, is adapted to permit its coils to be simultaneously active, and thus, unlike typical conical springs, the spring 14 has a linear force versus distance relationship. This is accomplished by increasing the pitch between the coils as the coil diameter increases. Such increasing pitch offsets the loss of the spring force caused by the increasing coil diameter, and thereby permits each of the coils of the conical spring 14 to be simultaneously active. Therefore, the force versus distance relationship of the spring 14 is substantially linear.

The relationship between the coil diameter and coil length for a single coil spring is defined by the expression:

$$X_L = \frac{8A}{Gd^4} D^3 \qquad (8)$$

where X_L is the relaxed length of the single coil, A is the desired force of the coil when fully compressed, G is the modulus of the wire, d is the wire diameter, and D is the coil diameter. Since A is the desired force of the spring and G and d depend on the type of spring wire used, the expression $8A/Gd^4$ will be a constant, or K'. Thus, for a spring of given material and given force, the coil length is equal to the cube of the coil diameter times the constant K', and equation (8) may be rewritten as:

$$X_L = K'D^3 \qquad (9)$$

This expression forms a curve 76, as shown in Figure 11. Through an iterative process, various points on the curve 76 are chosen to produce a series of coils having progressively decreasing diameters which, when connected, form a spring of the desired conical shape. Such conical shape should, of course, permit the coils to

nest within one another when the spring is fully compressed. Further, the largest coil diameter should not exceed either dimension of the central plates 16 to permit it to be retained by the spring cup 34. It should be noted that, since coils of decreasing diameter must be joined together to form the conical spring, each coil will have a diameter on one end that is smaller than that of the other end. Thus, the coil diameters of the curve 76 represent mean coil diameters, and the end diameters of the coils must be adjusted accordingly to permit the coils to be joined together to form a conically-shaped spring. As will be apparent to those skilled in the art, such adjustment may be accomplished during the winding of the spring with the mean coil diameter and coil pitch serving as guidelines. It has been found that the following mean coil diameters produce an essentially conical spring that permits the coils to nest when fully compressed:

Coil # 1 - 1.5	Coil # 3 - 2.25
Coil # 2 - 1.88	Coil # 4 - 2.5

Preferably, the modulus of the wire is 75.8 G Pa, the wire diameter is 2.54 mm and the force at full compression is about 111.2 N. Given these values, the pitch of each of the above-listed coils may be calculated, using equation (8), as follows:

Coil #1 - .6	Coil #3 - 2.05
Coil #2 - 1.19	Coil #4 - 2.8

It should, however, be emphasized that, whatever spring characteristics are chosen, the maximum stress on the spring, when fully compressed, should be no more than about one-half of its yield point stress. This permits the spring to be stored for substantial periods of time in its fully compressed state without seriously affecting the spring characteristics.

The conical spring 14 is formed according to the foregoing inventive concepts to generate a substantially linear force versus distance curve which approximates the desired force versus distance curve 74 (Figure 10) created by the plate geometry. Thus, since the cur.e 74 defines the spring characteristics necessary to maintain a constant vacuum within the reservoir 40, and the spring 14 approximates such spring characteristics, the reservoir vacuum will be substantially constant throughout its filling range. Test results using the plate geometry and spring coil diameters previously described confirm that a substantially constant vacuum (i.e., within 20% may be achieved through 45 degrees of theta, as shown by the curve 78 of Figure 12.

Although the above-described plate geometry is designed to interact with a spring having a linear force versus distance relationship, it will be understood that the plate geometry may be changed to permit it to interact with springs having various other force/distance relationships, so long as the plate geometry reduces the effective plate area against which the spring force is applied at a rate which permits concommitant reductions in spring force to produce a substantially constant vacuum in the reservoir. In other words, a substantially constant vacuum may be achieved by using various combinations of plate geometry and springs, provided that the force versus distance requirements defined by the plate geometry at least approximate the force versus distance characteristics of the spring.

Referring to Figure 12, approximately 350 cc of fluid will have been drawn into the reservoir 40 when theta reaches 45 degrees. Since the dimensions of the reservoir 40 prevent the plates 10 from separating beyond a distance equivalent to a theta of 45 degrees,

the reservoir vacuum will not be maintained thereafter, and therefore, the vacuum will rapidly decrease to zero. An additional amount of fluid will be drawn into the reservoir during the period that such decrease of the reservoir vacuum occurs. Such additional fluid will be accommodated by the reservoir 40, since, as the vacuum decreases, the side walls 68,69, will be permitted to bow outward.

The reservoir 40 should preferably be of a polyvinyl chloride material having a thickness of 0.254 mm to 0.762 mm and a durometer shore A of 75 to 100. Such reservoir material has sufficient flexibility to permit the plates 10 to separate without being inhibited by the reservoir 40. However, the material is sufficiently inelastic to permit it to maintain its shape and prevent deformation due to the weight of fluid in the reservoir 40. Further, the material is sufficiently strong to resist puncturing, and is compatible with gamma-radiation sterilization.

The plates 10 are preferably formed of a polypropylene material, which is also compatible with gamma-radiation sterilization. Such material is sufficiently rigid to prevent the spring 14 from deforming the plates 10 and is sufficiently strong to permit the hooking surfaces 56 of the latch 35 to hold the plate 10 together. However, the material is sufficiently flexible and resilient to permit the biasing tabs 64 and the integrally formed or "living" hinges 17 of the plates 10 to function properly.

CLAIMS

1. A surgical evacuation device comprising a compressible reservoir which expands in use by spring action to draw fluid from a wound into the reservoir, characterised in the the reservoir comprises:

a flexible membrane (40);

first and second articulated walls (10a, 10b) which cooperate to form an aticultive structure for supporting the membrane; and

a spring (14), between said walls (10a, 10b) and biasing them apart to expand the reservoir and create a vacuum therein, and whose force on the walls decreases as the reservoir expands, the articulative structure defining a shape for the reservoir which varies as the reservoir expands to at least partially offset the decreasing force of the spring (14) to reduce changes in reservoir vacuum.

2. A device as claimed in claim 1, characterised in the variation of the shape of the structure decreases the effective wall area acted upon by the force of the spring (14).

3. A device as claimed in claim 1 or 2, characterised in that variation of the shape of the structure permits atmospheric forces on the articulated walls to provide a correspondingly varying supplementary force to assist the spring (14) in biassing the walls (10a, 10b) apart, the supplementary force increasing as the reservoir expands to cooperate with the force of the spring to reduce changes in vacuum as the reservoir expands.

4. A device as claimed in any of claims 1 to 3, characterised in that it also comprises a latch (35), inside the reservoir, adapted to hold selectively the articulated walls (10a, 10b) together in close proximity

to each other.

5. A device as claimed in claim 4, characterised in that the reservoir is pre-evacuated to assist the latch (35) in holding the articulated walls (10a, 10b) together and to prevent deformation of the latch (35) when the device is stored.

6. A device as claimed in claim 4 or 5, characterised in that the latch comprises:

a first latch hook (36a) on the first articulated wall (10a);

a second latch hook (36b) on the second articulated wall (10b); and

said first and second latch hooks including first and second biasing cam surfaces (58a, 58b), and first and second hooking surfaces (56a, 56b), respectively the first and second cam surfaces (58a, 58b) cooperating to move the hooking surfaces to a position which permits them to engage.

7. A device as claimed in any of claims 4 to 6, characterised in that:

the first articulated wall (10a) comprises a first wing wall member(18a) pivotally connected to a first central wall member (16a) by a first hinge (17a);

the second articulated wall member (10b) comprises a second wing wall member(18b) pivotally connected to a second central wall member (16b) by a second hinge;(17b);

the first and second hinges (17a, 17b) being (i) positioned to permit the wing wall members (18a, 18b) to pivot relative to the central wall members (16a, 16b) and (ii) formed to force the first and second central wall members (16a, 16b) to slide relative to each other when the first and second wing wall members (18a, 18b) pivot relative to the central wall members; and

the latch (35) being disengageable by the relative

sliding of the central wall members (16a, 16b).

8. A device as claimed in any of claims 1 to 6, characterised in that:

the membrane comprises a plastics bag (40) containing and sized to the articulative structure;

wherein the first and second articulated walls (10a, 10b) comprise a pair of congruent, superimposed, hinged plates;

each plate comprising a generally square or rectangular central member (16a, 16b) hingeably connected at opposite edges between wing members (18a, 20a; 18b, 20b);

each wing member having a generally isosceles trapezoidal shape with its longest side remote from the associated central member; and

two of said longest sides being hingeably connected to form the articulative structure.

9. A device as claimed in any preceding claim, characterised in that the spring (14) has coils which nest within one another to permit the articulated walls to lie flat against one another when the spring is fully compressed.

10. A device as claimed in any of claims 1 to 9, characterised in that the spring (14) has coils formed to nest within each other when the spring is fully compressed, and formed to cause all of the coils, when compressed, to be active.

11. A device as claimed in any of claims 1 to 9, characterised in that the spring (14) has coils formed to next within each other when the spring is fully compressed, the coils being formed to cause the force of the spring to vary linearly with the distance it expands from full compression.

12. An articulated plate, for use as a component

in a surgical evacuation device according to any of claims 1 to 11 and adapted to form at least a part of the the articulative structure therein, characterised in that the plate comprises:

a generally square or rectangular central member (16a) hingeably connected at opposite edges between wing members (18a, 20a);

each wing member (18a, 20a) having a generally isosceles trapezoidal shape with its longest side remote from the central member (16a); and

said longest side having means for hingeable connection with the corresponding side of another such plate.

13. Use of a device according to any of claims 1 to 11 to remove fluid from a wound.

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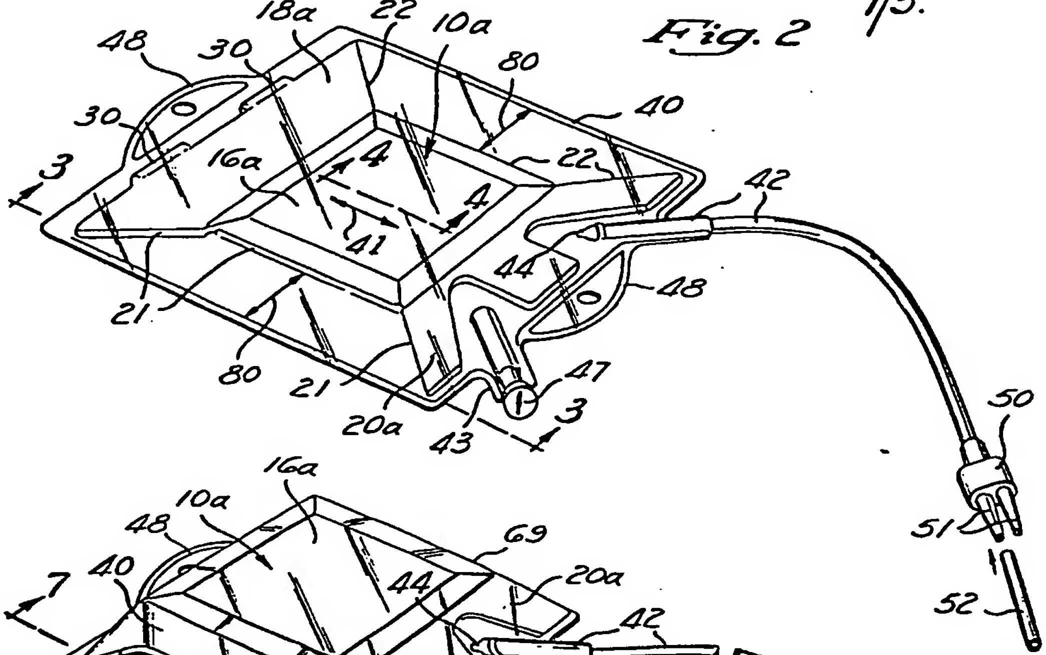

Fig. 2

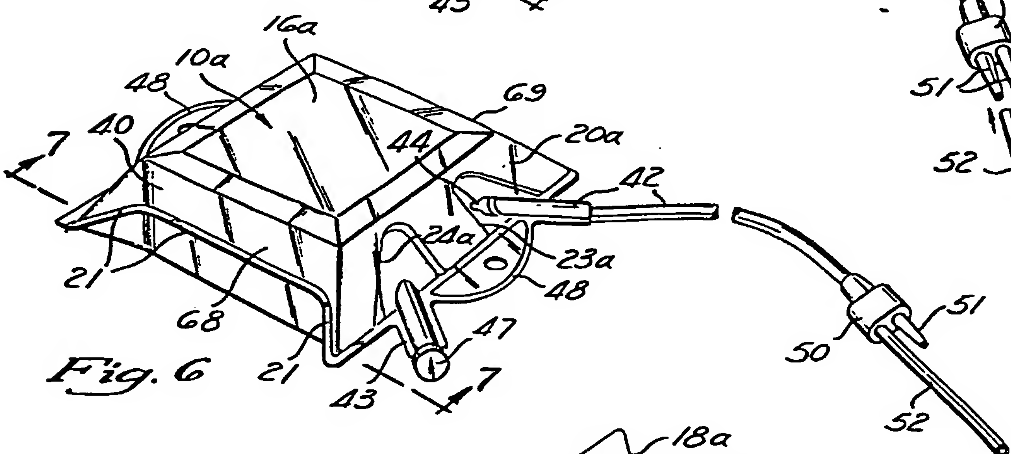

Fig. 6

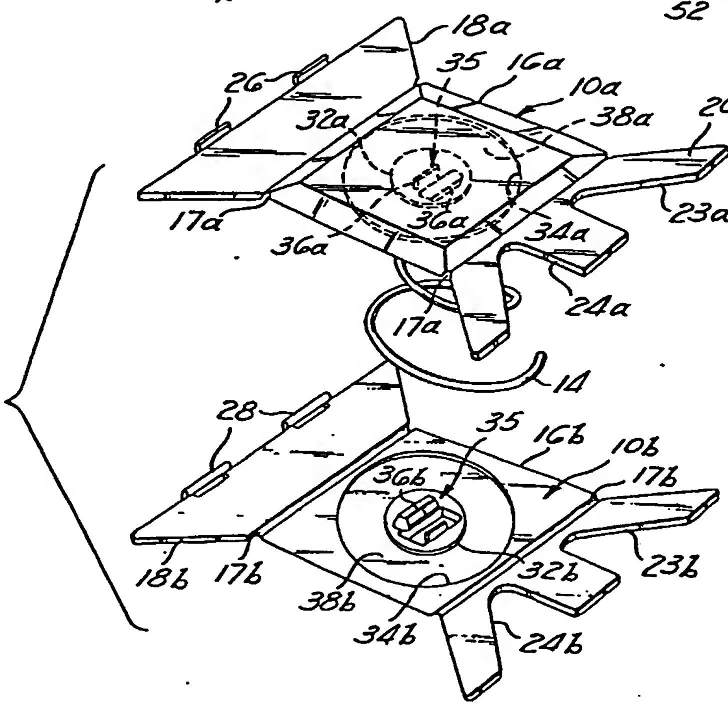

Fig. 1

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Fig. 3

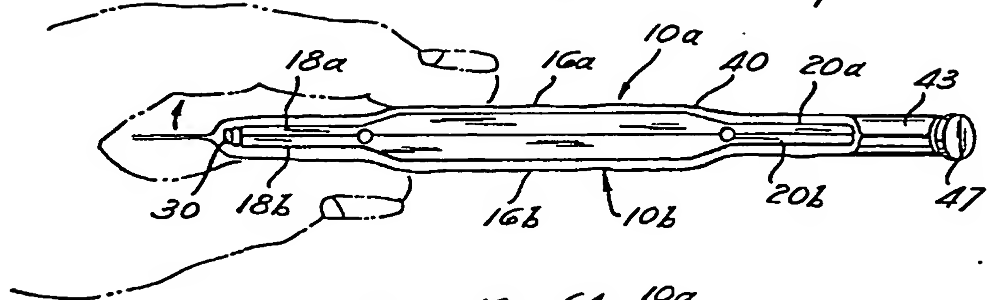


Fig. 7

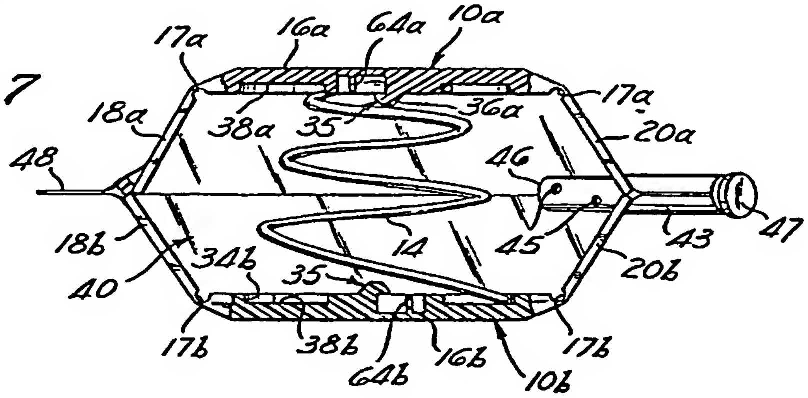
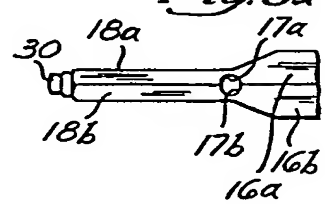


Fig. 3a



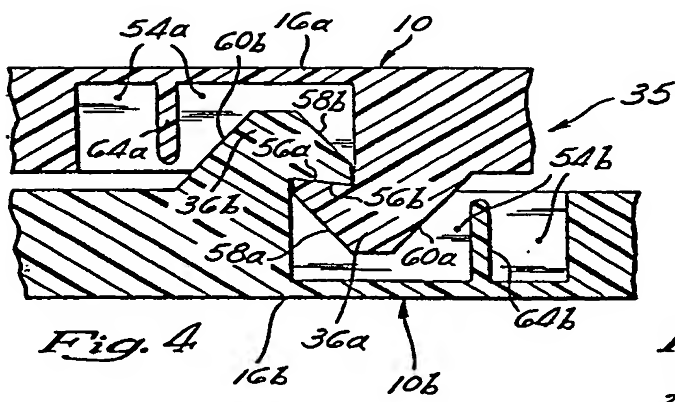


Fig. 4

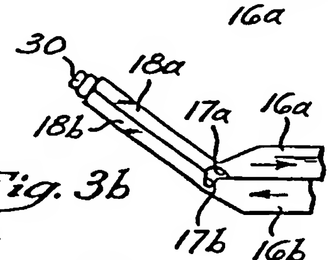


Fig. 3b

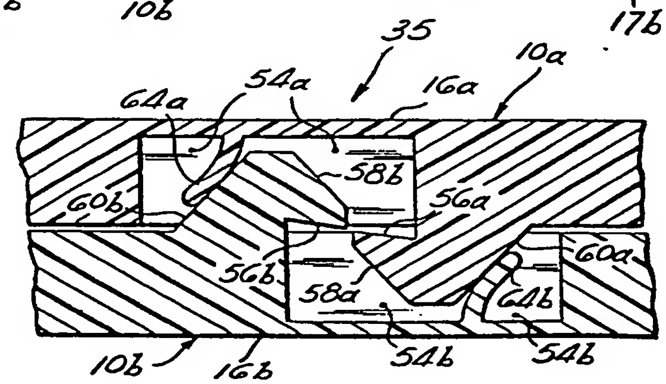


Fig. 5

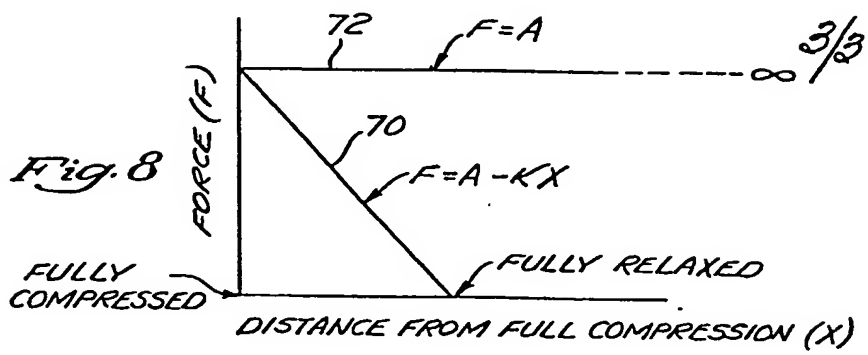


Fig. 8

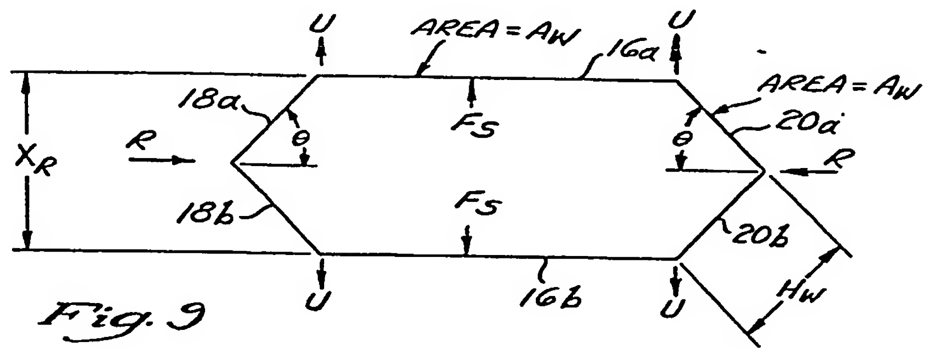


Fig. 9

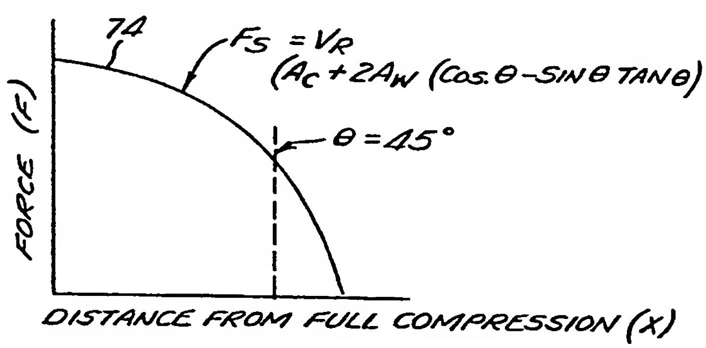


Fig. 10

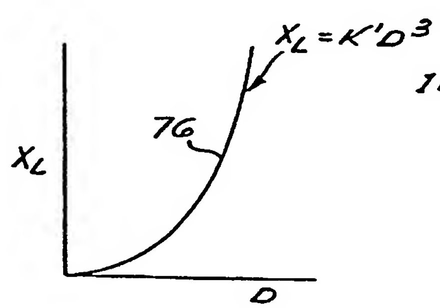


Fig. 11

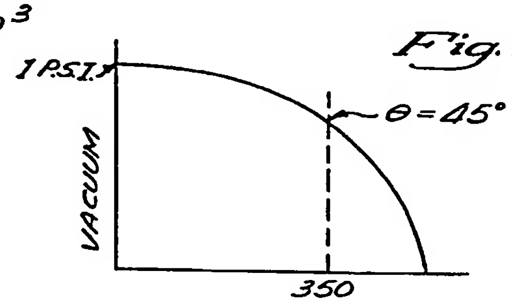


Fig. 12

European Patent Office

EUROPEAN SEARCH REPORT

0048164

Application number
EP 81 30 4237

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.[3])
	DE - A - 2 500 391 (G. GÜNTHER) * the figures; page 3, paragraph 1 to page 5, paragraph 1 *	1,3,7, 8,12, 13	A 61 M 1/00
D	US - A - 4 161 179 (H. ABRAMSON) * figures 1,10; column 2, lines 11-35; column 3, lines 47-52 *	1-3,5, 13	

TECHNICAL FIELDS SEARCHED (Int. Cl.[3])

A 61 M

CATEGORY OF CITED DOCUMENTS

X: particularly relevant
A: technological background
O: non-written disclosure
P: intermediate document
T: theory or principle underlying the invention
E: conflicting application
D: document cited in the application
L: citation for other reasons

&: member of the same patent family, corresponding document

X The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	15.12.1981	VEREECKE

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